MTI PRECISION PRODUCTS
175 Oberlin Avenue
Lakewood, New Jersey 08701

K070001

510(K) Submission		
PREPARED BY: Tod Brenner		APPROVED BY: Joseph Deluca
DATE: 12/23/06		DATE: 12-23-06

TITLE: LUBE FREE LOW SPEED HANDPIECE PRODUCT LINE

SECTION 5: 510(k) SUMMARY

FEB - 2 2007

The following submission has been prepared pursuant to requirements specified in 21CFR, Para 807.92

Contact Information:

Tod Brenner, Vice President, Engineering and Manufacturing
MTI Dental Products
175 Oberlin Ave., North
Lakewood, NJ.
08701
Phone: 732-905-7440
Fax: 732-905-7445

Date: October 25, 2006

Trade Names:

Master Classic 5K Low Speed Handpiece
Master Classic 20K Low Speed Handpiece
Master TM5 Low Speed Handpiece
Master TM20 Low Speed Handpiece

Common Name:

Low Speed Air Driven Dental Handpiece

Classification Name:

Handpiece, Air-Powered (21 CFR 872.4200)

Classification Product Code:

EFB

Predicate Devices:

Lynx Classic 5K	Classic Air Motor	K940261
Lynx TM5 - 5K	Torquemaster	K940261
Lynx TM20 - 20K	Torquemaster	K940261

Device Description:
The Master line of air driven handpieces are intended for use in a variety of non-surgical dental laboratory and operatory applications. They are typically coupled with a selection of attachments and angle heads to provide the licensed practitioner with the correct range of torque and speed to perform the desired procedure.

Intended Uses:
The Master product line of air motors will be used in dental laboratory and operatory non-surgical procedures by licensed practitioners.

The following are examples for which the motors can be utilized. Note that these are just examples and not limitations of the procedures for which the handpieces can be used.

- Grinding and trimming on dentures and bridge work.
- Polishing and finishing of natural dentition
- Endodontic access procedures
- Cavity preparation.
- Crown and cap preparation
- Post and pin setting
- Implant setting

The handpieces utilize materials commonly known for their ability to withstand many exposures to common cleaning and disinfecting agents and steam sterilization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Tod H. Brenner
Vice President
MTI Precision Products
175 Oberlin Avenue North
Lakewood, New Jersey 08701

FEB - 2 2007

Re: K070001
Trade/Device Name: Master Classic 5K Low Speed Handpiece Master Classic 20K Low Speed Handpiece Master TM5 5K Low Speed Handpiece Master TM20 20K Low Speed Handpiece
Regulation Number: 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: December 5, 2006
Received: January 3, 2007

Dear Mr. Brenner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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DATE: 12/23/06		DATE: 12-23-06

TITLE: LUBE FREE LOW SPEED HANDPIECE PRODUCT LINE

SECTION 4: STATEMENT OF INDICATIONS FOR USE

The Lube Free Low Speed Handpiece line comprises a family of air driven low speed dental motors, FDA classification code EFB, for use in dental non-surgical operatory and laboratory procedures by licensed practitioners. The dental motors are known as:

Master Classic 5KLow Speed Handpiece
Master Classic 20K Low Speed Handpiece
Master TM5 5K Low Speed Handpiece
Master TM20 20K Low Speed Handpiece

The following are examples for which the motors can be utilized. Note that these are just examples and not limitations of the procedures for which the handpieces can be used.

- Grinding and trimming on dentures and bridge work.
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(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K070001